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Publix Super Markets, Inc.

Controlled Substance Anti-Diversion Processes

Publix

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About This Document

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Chapter 1: Overview

Introduction

The purpose of this guide is to provide an overview of the processes performed by multiple Publix departments to identify and prevent controlled substance diversion. Departments that contribute to this effort include:

- Loss Prevention
- Pharmacy Operations
- Pharmacy Procurement Department
- Warehousing and Distribution

In this chapter

This chapter contains the following topics.

Documentation Scope

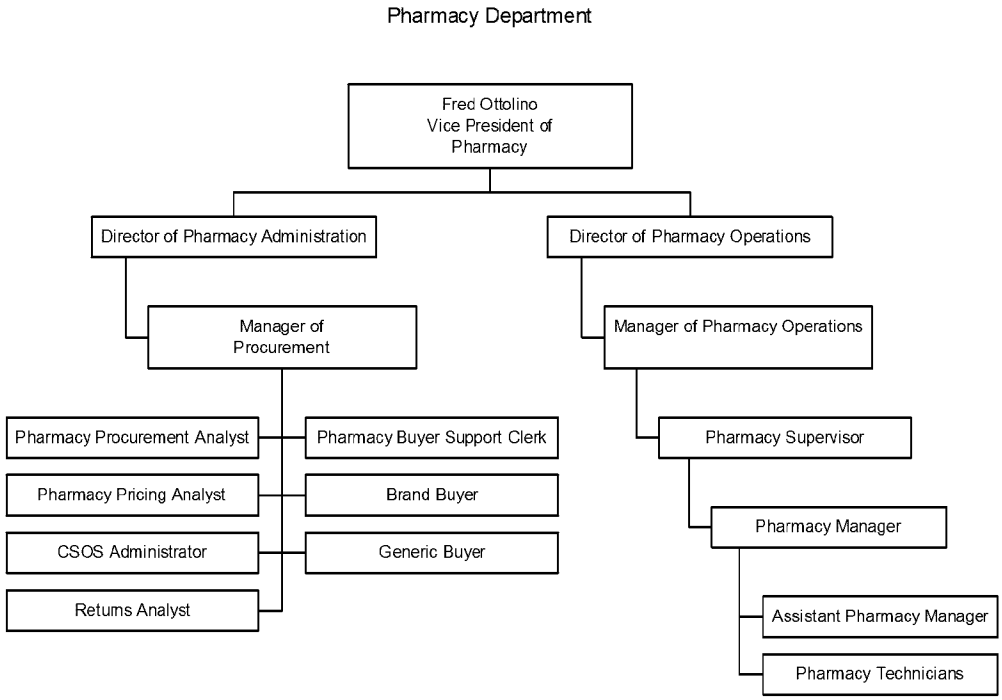
Scope

This guide provides a basic overview of each department's role in preventing controlled substance diversion. Each department is expected to maintain their own detailed procedures.

Pharmacy Operations Organization Structure

Pharmacy Operations

Below is the organization structure for Pharmacy Operations (note: department personnel not involved in controlled substance diversion prevention are not identified on this organization tree). Reference to these associates role with controlled substance diversion will be made throughout this guide.



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Chapter 2: Loss Prevention Processes

Overview

Introduction

The purpose of this chapter is to outline the processes conducted by Loss Prevention to detect and prevent controlled substance diversion. The document provides a brief explanation of each of the tools the Loss Prevention and Safety Department has in place for reviewing exceptions and trends regarding Controlled Substance purchasing and dispensing.

In this chapter

This chapter contains the following topics.

Shrink Audit- Pharmacy

Overview

Stores are randomly selected to be audited for shrink/theft by Loss Prevention Auditors (LPA) and Loss Prevention Specialists (LPS) each year. LPA and LPS randomly select stores for a Shrink Audit each year. This audit includes a Pharmacy section comprised of questions to identify discrepancies with controlled substance inventory. LPA/LPS randomly selects 5 controlled substance NDCs for verification. The pharmacist must pull each designated NDC and provide an inventory count to the LPA/LPS. The LPA/LPS then compares the amount counted to the balance on hand in the Enterprise Pharmacy System. Corporate LP Support can request additional reporting for further inquiry if any discrepancies are identified.

Weekly Pharmacy Inventory Adjustment Exception Reporting

Overview

Corporate Loss Prevention Support creates a Weekly Pharmacy Adjustment Exception Report and analyzes exception results for concerns, patterns, and unexplained activity. Cases are opened for investigation in the Loss Prevention Management System and documented accordingly by the assigned LP Specialist. The Loss Prevention Specialist works with the Pharmacy Supervisor to install surveillance equipment or to conduct other research considered pertinent to the investigation.

The Weekly Pharmacy Inventory Adjustment Exception Report includes:

- NDC's for Controlled CII-CV pills, capsules, and tablets,
- adjustments at the GCN level where +/- one full bottle was adjusted for any reason code except Dispense, Undispense, Received from Supplier, and Return to Supplier, and
- trends over time to evaluate if a store appears on the exception report for multiple weeks.

Chapter 3: Pharmacy Operations Processes

Overview

Introduction

Procedures for Pharmacy Operations to prevent controlled substance diversion are documented in the Pharmacy Rules and Procedure Guide. Pharmacists have a responsibility to ensure their controlled substance inventory is secure and accurate, in addition to a corresponding responsibility to ensure the prescriptions written by prescribers are for a valid medical purpose. This chapter documents these responsibilities.

In this chapter

This chapter contains the following topics.

Pharmacy Operations Background

Background

The Pharmacy Operations Department consists of retail pharmacy staff (pharmacists and technicians), Pharmacy Supervisors, Pharmacy Operations Managers, and the Director of Pharmacy Operations. This department reports to the Vice President of Pharmacy (see Pharmacy Organization Structure section 1-3).

Pharmacy Supervisors are responsible for ensuring Publix Pharmacy staff are compliant with all current pharmacy laws and regulations, including those related to controlled substances.

Publix Controlled Substance Policy

Purpose

Publix is committed to providing and maintaining a working environment free of substance abuse. The following provides an overview of Publix's Substance Abuse Policy.

Prohibited Conduct

The following is prohibited under Publix's Substance Abuse Policy:

- selling or distributing any drug, including a prescription drug, whether on or off duty, unless the associate is legally authorized to sell or distribute the substance in question under the circumstances
- possessing any illegal drug on Publix premises at any time
- using any illegal drug at any time (This includes out-of-date or expired prescription drugs, prescription drugs prescribed for someone else, or current prescription drugs not used according to the prescription. Medications over 24 months old are considered out-of-date when prescribed on an as needed basis.) and
- drinking alcohol while on the job or reporting to work under the influence of alcohol.

Drug Testing

Applicants that are offered a position at Publix are drug tested before they are allowed to begin employment. Associates working for Publix are subject to random drug testing. The method and location of testing are chosen by Publix. Refusal to submit to testing is failing to:

- appear for a test within the required timeframe
- remain at the collection site until the testing process is complete
- provide a specimen or cooperate with any part of the testing process and
- provide a sufficient amount of urine without a valid medical explanation.

Applicants who refuse to submit to testing will be ineligible for employment for a minimum one year. Associates who refuse to submit to testing should be terminated.

Pharmacy Controlled Substance Manual Inventory Adjustment Report (Summary and Full Detail)

Overview

Two Controlled Substance Manual Inventory Adjustment reports are uploaded to Document Direct every Wednesday. These reports are titled:

1. Controlled Substance Manual Inventory Adjustment Rpt **Summary**
2. Controlled Substance Manual Inventory Adjustment Rpt **Full Detail**

Pharmacies are instructed to print their report, review adjustments made, add adjustment descriptions (reasons adjustments were made), and sign off on the report. Pharmacy Supervisors must review the Controlled Substance Manual Inventory Adjustment Report during monthly pharmacy visits.

The full detail report contains what adjustment reason the pharmacy selected and is reviewed by Pharmacy Supervisors and Pharmacy Operations Managers.

Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing

Overview

To minimize the dispensing of controlled substances based on fraudulent representations, pharmacy associates must first identify suspicious activity or prescriptions. If a pharmacy associate discovers a suspicious or fraudulent controlled substance prescription the pharmacist on duty is notified and the prescription is not filled until its validity can be verified.

Examples of suspicious activity

Pharmacy staff must always use professional judgment to assess suspicious situations. This list describes potential suspicious activity that may indicate an invalid controlled substance prescription:

- The prescriber's practice is not near where the patient resides.
- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the area.
- The patient appears impaired or his/her behavior is suspicious.
- The patient appears to be returning too frequently. (i.e. prescription which should have lasted for a month in legitimate use is being refilled on a biweekly, weekly or even a daily basis.)
- The patient requests early refills or states that the previous fill was lost or stolen.
- The patient changes prescribers frequently (“doctor shopping”).
- The patient has multiple controlled substance prescriptions.
- A new patient presents a prescription for a large quantity of a controlled substance.
- The patient only pays cash for controlled substance prescriptions.
- The prescriber writes prescriptions for central nervous system (CNS) drugs, such as depressants and stimulants, at the same time. Some drug abusers often request prescriptions for "uppers and downers" at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of patients appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- Numerous people who are not regular patrons or residents of the community, suddenly show up with prescriptions from the same physician.

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Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing, Continued

Guarding against filling fraudulent prescriptions

Pharmacy associates are instructed to take the following actions in reviewing a controlled substance prescription.

- Carefully examine controlled substance prescriptions against the DEA and state requirements.
- Evaluate that any faxed, transmitted, or orally prescribed prescriptions meet DEA and state requirements.
- Verify that controlled substance prescriptions are written on the required tamper resistant form when required by law. Note: For Florida, use the Approved Vendor Verification link on the pharmacy portal for assistance.
- Check the prescription to determine if any information on the prescription has been altered.
- Check the prescriber's signature to make sure that it appears legitimate.
- For prescriptions submitted by phone, verify that the call came from the prescriber's office (e.g., if unsure or suspicious, call the office back using the phone number from our records).
- For prescriptions submitted by phone, verify that the caller is on the prescriber's staff (e.g., if unsure or suspicious, the pharmacist must call the office back using the phone number from our records).
- For faxed prescriptions verify the fax transmission came directly from the prescriber's office.
- Call the prescriber using the number on file if there are any questions.
- Check the person's identification and verify that it is the person named on the prescription at the time of pickup.

Controlled Substance Cycle Counts

Annual Controlled Substance Inventory

The Controlled Substance Act requires that each registered Pharmacy complete an accurate controlled substance inventory every two years. Publix elects to take an ending inventory *each* year. All states, except Alabama, should take an annual controlled substance ending inventory on December 31st or a beginning inventory on January 2nd. Alabama state law requires that the on-hand inventory be taken on January 15th each year.

Pharmacists must take an *exact count* of
- all unopened and opened C-II controlled substances
- unopened C-IIIs, C-IVs, and CVs and
- opened C-IIIs, C-IVs, and CVs that are more than 1,000 count.

Note: The quantity for opened packages of C-III through C-V controlled substances containing less than 1000 pills is estimated.

Monthly CII inventory audit

C-II monthly variances are tracked and reported each month. Pharmacists alternate conducting the monthly CII inventory audit by comparing the physical count of each item to the system report – Inventory Valuation. Once the audit is complete, pharmacists are required to explain any variances between the pharmacy system on-hand quantities and the physical counts on the CII Monthly Variance Report form. All monthly audits are sent to Pharmacy Supervisors for review.

Reporting variances/ significant losses/theft

Pharmacists contact their Pharmacy Supervisor to help determine whether a loss is "significant." Thefts and/or significant losses are reported to the DEA within one business day of discovery. The pharmacist contacts their Pharmacy Supervisor to prepare the report which is a short statement that is faxed to the local DEA office. Once circumstances surrounding the theft and/or significant loss are clear the DEA is notified using *DEA Form 106*.

Prescription Drug Monitoring Programs

Overview

Publix operates in multiple states. Each state has developed an online Prescription Drug Monitoring Program (PDMP) to record all controlled substance prescriptions filled in the particular state. The program gives pharmacists the ability to look at a patient's purchase history of controlled substances. Pharmacists utilize the information to make professional judgments about whether or not to fill a controlled substance for a patient.

Expectations

Publix Pharmacists should use the website database to help determine whether or not dispensing certain controlled substance prescriptions is appropriate. Examples of circumstances of when to use the database are listed below:

- A new patient to Publix with a prescription for a large quantity of a controlled substance
- A patient pays cash for controlled substance prescriptions
- A patient has multiple controlled substance prescriptions
- A patient requests early refill or states a previous fill was lost or stolen
- A patient appears impaired or behavior is suspicious
- Any time a Pharmacist determines that it is necessary to check the patient's history

Handling results

If the PDMP shows that the customer is filling prescriptions at multiple pharmacies, purchasing excessive quantities of controlled substances, filling prescriptions early or using multiple doctors, the pharmacist informs the customer that the controlled substance prescription cannot be filled.

- For an *existing customer*, the decision is documented in a *Patient Note* (example: Checked PDMP website - Patient filling CS Rxs at multiple pharmacies).
- For a customer who is not in our system, no further action is needed.

If the Rx is filled after reviewing the patient's history in the database, the pharmacist documents the decision in an *Rx Note (i.e.,* "Checked PDMP website") and fills the prescription.

Chapter 4: Pharmacy Procurement Department Processes

Overview

Introduction

This chapter will review the Pharmacy Procurement Department processes that assist in preventing controlled substance diversion.

In this chapter

This chapter contains the following topics.

PIMS Ship Max Quantities

Overview

Ship max quantities are the maximum amount of an item (in full containers) that can be purchased on a single order from the Publix Pharmacy Warehouse. Ship maximums are entered when the item is created and periodically reviewed by the Pharmacy Manager of Procurement.

When a Publix Pharmacy Warehouse order is transmitted to the warehouse for a quantity that exceeds the Ship Max, the order is only fulfilled to the maximum quantity and the remaining quantity is omitted.

Pharmacy Controlled Substance Auditing Program

Overview

The Pharmacy Controlled Substance Auditing Program was designed to prospectively review controlled substance orders before fulfillment from the Publix Pharmacy Warehouse. A key component to this program is the creation of a monthly purchasing threshold by molecule for each pharmacy. Molecules include all of the unique strengths and formulations of a particular controlled substance (for example, the alprazolam molecule would include alprazolam 0.25, 0.5, 1, and 2mg as well as the extended release strengths).

Monthly thresholds are:

- created based on an analysis of historical purchasing patterns, actual pharmacy usage, and usage compared to the average Publix pharmacy,
- initially entered by the Pharmacy Procurement Department,
- can only be increased through a threshold increase process that requires Pharmacy Supervisor approval with oversight from the Pharmacy Operations Manager

Order quantities of controlled substances throughout the month are aggregated and compared to the monthly threshold. Once the monthly threshold is met, no additional orders for any item in that particular molecule will be shipped for the remainder of the month. An email notification is sent to the pharmacy and the Pharmacy Supervisor when the pharmacy is approaching their threshold and when they have exceeded the threshold.

Note- Pharmacy Supervisors should visit pharmacies that have exceeded their thresholds to:

- determine the need for a threshold increase,
- determine if any suspicious dispensing activity is taking place.

If suspicious activity is confirmed:

- Pharmacy Supervisors must notify their Pharmacy Operations Manager and the Manager of Procurement immediately, and
- the Manager of Procurement must notify the Orlando DEA office immediately and de-authorize any implicated controlled substances from being shipped to the pharmacy from the Pharmacy Warehouse.

Controlled Substance Dispensing Reporting

Overview

Each month a report is generated by the Procurement Department that aggregates each pharmacy's dispensing history for high diversion controlled substances. This report is used by Operations to:

- identify and evaluate trends in dispensing (percentage of cash prescriptions, percentage of controlled substances, etc.)
- compare pharmacy controlled substance dispensing from similar volume pharmacies.
- recommend adjustments to controlled substance thresholds.

The report contains the following by individual store:

- count of all controlled substance prescriptions dispensed
- % of controlled substance prescriptions to overall prescriptions
- count and % of prescriptions for individual controlled substances
- count of controlled substance prescriptions filled cash or discount card
- % of controlled substance prescriptions filled cash or discount card.

Controlled Substance Ordering System (CSOS) Excessive Order Review

Overview

Publix utilizes central Controlled Substance Ordering System Administrators (CSOS Administrators) to sign all electronic CII orders for Publix Pharmacies. Publix CSOS Administrators evaluate orders for reasonableness prior to signing them.

Order points for controlled substances are set by using the Central Inventory Management tool. This tool increases or decreases the min/max values according to the pharmacy's actual usage of drugs. Sometimes pharmacies order more than their normal usage. When this happens, the CSOS Administrator needs to verify usage prior to signing the order to determine if the large quantity is appropriate for the pharmacy or if the quantity being ordered is too high. They do this by using the following data:

- Dispensing history
- Current inventory
- Allocated inventory from recent prescription activity
- Prescription hard-copy review

If the quantity ordered is too high, it must be sent to the Manager of Procurement for authorization or cancellation.

Chapter 5: Pharmacy Warehouse Processes

Overview

The Pharmacy Warehouse Processes to identify and prevent diversion are listed in this chapter.

In this chapter

This chapter contains the following topics.

Security

Employee security

Due to the higher security standards required to handle pharmaceuticals, associates are required to be fingerprinted and have a background check conducted prior to beginning employment. Random background checks and drug screens are conducted on existing employees.

Warehouse Security

The following security measures are in place to ensure the security of the Pharmacy Warehouse product:

- Security Officers are assigned to the Pharmacy Warehouse to control access and enforce security procedures at all times the facility is occupied.
- All Security Officers assigned to the Pharmacy Warehouse are required to possess (or obtain within 30 days of employment) a Class D license issued by the Florida Department of Agriculture and Consumer Services.
- All Security Officers must successfully complete a background investigation that includes criminal records check and drug screen.
- An alarm system will alert security if any perimeter entry/exit access points are opened without authorization.
- Each entry/exit access point has a sounder and strobe, which serves as a functional and practical deterrent to unauthorized entry into the warehouse.
- Interior motion detectors are installed on the shipping and receiving docks, lobby, equipment door and all cages to detect activity when warehouse associates are not present.
- A closed circuit television is installed to provide observation and continuously record interior and exterior of the facility.
- Perimeter dock and aisle lighting illuminates the respective area at all times.
- Associates or other individuals removing Publix material or equipment from the Pharmacy Warehouse must obtain written authorization that describes the item to be removed, the date and the signature of the Site Manager, Pharmacy Warehouse Department Manager, Lead Associate or QA associate.
- All trash is staged in a designated area for inspection by the Security Officer or a Pharmacy Warehouse Supervisor. After inspection, the trash is immediately removed from the facility.

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Security, Continued

Warehouse Security, Continued

The Publix Pharmacy Warehouse has an access control system to prevent unauthorized entry into the facility and restricts access to the prescription drugs stored within the facility.

Security ensures that only associates with a legitimate business need in the prescription drug storage and handling areas have access to those respective areas.

Third parties such as vendor representatives, government inspectors or law enforcement officials must have a legitimate business purpose for being authorized access to an area where product is stored or handled. Third parties are escorted by the Distribution Center Site Manager, Pharmacy Department Manager, Lead associate, QA associate or Facility Security Supervisor. Anyone that enters or leaves an area where product is stored is subject to a search by security.

The control cage is further restricted by badge access solely for employees who have responsibilities that require access. All other employees are restricted from entry.

Security cameras monitor the entire cage 24 hours a day, 7 days a week.

Cycle Counts

Cycle Count Process

A complete and accurate record of all prescription drugs must be made annually by establishments permitted under Chapter 499, F.S. A physical inventory must be conducted at least annually unless perpetual inventory records are maintained, in which case the physical inventory may be conducted on a biennial basis. **Selection (Working) Locations** are the locations where product is selected (worked) from. These locations hold cases which have been opened so that the selector may pick individual units for store orders.

Reserve Locations are the locations where product is stored in full quantities. Product is taken from these locations and placed in the working/selection locations as needed.

This table shows the frequency of inventory counts for Working and Reserve locations:

	Schedules 3,4 and 5 (Controlled)	Schedules 6 and 8 (Non-controlled)
Location	**Frequency of inventory**	
Selection	Twice Daily	Once Weekly
Reserve	Every 6 Months	Every 6 Months
*Selection & Reserve	Biennial (every two years)	Biennial (every two years)

*Pursuant to Rule 64F 12.012(2)(e), a complete inventory record is required every two years. This inventory record is to be filed in a separate file titled "DEA Biennial Inventory".

The QA Specialist will use Selection and Reserve *Cycle Count Tracking Sheets* to log the date when locations are counted. This will ensure inventories are complete and timely.

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Cycle Counts, Continued

Cycle Count Process, continued

Accurate inventory counts are maintained using a three-person system and "blind" count books. The counter, reviewer and data entry associates must be three *different* associates as defined below:

- Counter- Any associate may be asked to perform a count.
- Reviewer- The Distribution Center Site Manager, Department Manager or associate appointed by a manager to review count books
- Data Entry- The QA associate is responsible for documenting and making inventory adjustments (data entry) and ensuring that all documentation and adjustments are in compliance with regulations and governing recordkeeping. The Department Manager, QA associate or Inventory associate may all perform inventory adjustments as long as they have not acted as the counter or reviewer for that same count book.

An inventory associate generates both the count books and the answer books using the IIIRA screen in EXCEED 2000. The following two copies are required for each section to be counted:

1. "Blind" Count Book- lists location with item details excluding the balance on hand for each item in each location
2. Answer book- lists location with item details including the balance on hand for each item in each location

Count books for selection locations exclude full warehouse inventory. Count books for biennial inventories include all locations for an item (Selection *and* Reserve) to ensure a complete warehouse inventory.

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Cycle Counts, Continued

Cycle Count Process, continued

This table shows the physical inventory process:

Who	Does What
Inventory Associate	Print and hand out "Blind" Count books to Counter.
	Print Answer books for Reviewer
Counter	Counts each location listed on the "blind" book
	Signs the book
Reviewer	Identifies discrepancies using the answer book
	Signs the book
Were any discrepancies found by the reviewer? **If...** / **Then...** Yes / Inventory associate researches the discrepancy No / No action is necessary	
Data Entry	Adjusts the warehouse inventory as needed if the discrepancies are validated by the inventory associate's research
	Signs the book
	File a record of the adjustment and supporting documentation in the inventory office.

Selecting locations that contain controlled substances are cycle counted twice daily. Reserve locations are cycle counted every six months.

All selected controlled substance orders go through a second quality control process to verify the orders have been selected appropriately.

All deliveries containing controlled substances are opened at the time of receiving, and vendors are notified of any shortages/overages/damages promptly.